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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,872	04/25/2001	Antonio J. Grillo-Lopez	P 0280609/2000-30-154A	4921

909 7590 08/19/2003  
PILLSBURY WINTHROP, LLP  
P.O. BOX 10500  
MCLEAN, VA 22102

EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/840,872

Applicant(s)

GRILLO-LOPEZ, ANTONIO J.

Examiner

Gary B. Nickol Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,3-5 and 7.

Claim(s) withdrawn from consideration: 2,6 and 8-50.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: Attachment



Continuation of 2. NOTE: The suggested amendment whereby levels of the anti-CD20 antibody are greater in CSF than in serum would require further searching as it includes new parameters for consideration.

***Response to Arguments***

Claims 1 and 7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Maloney *et al.* (Blood, Vol. 90. No. 6, 1997, pages 2188-2195.) for the reasons of record in Paper No. 7, pages 5-6. Applicants argue (Paper No. 11, page 5) that the methods of Maloney *et al.* are directed to treatment of low grade non-Hodgkin's lymphoma that are not inclusive of methods for the treatment of CN lymphoma. This argument has been considered but is not found persuasive for reasons of record. The specification (page 10, lines 24-27) has defined the limitations of CNS lymphomas as those that are *inclusive* of non-Hodgkin's lymphoma (NHL). Thus, whether or not there is any pathological distinction between "low-grade" NHL and more "aggressive" lymphomas is irrelevant. The claims are indistinguishable from the prior art based on the definition of what is meant by a CNS lymphoma. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1, 5, and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Maloney *et al.* (Blood, Vol. 90. No. 6, 1997, pages 2188-2195.) as further evidenced by Yoneda *et al.* (US Patent No. 5,626,845, 1997) Applicants have reiterated their arguments with regards to Maloney *et al.*, and the rejection is maintained for the reasons set forth above and for the reasons of record.

Claims 1,3,5,7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,776,456 (Anderson *et al.* ) as evidenced by Murphy *et al.* (Clinical Oncology, 2<sup>nd</sup> edition, 1995,

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American Cancer Society, Inc.) and Kuppers *et al.* (Ann Oncol, 1998, Vol. 9 Suppl 5, abstract ) in further view of Yoneda *et al.* (US Patent No. 5,626,845, 1997) for the reasons of record.

Applicants have argued (Paper No. 10, page 7) that the Examiner has ignored known clinically relevant differences among lymphomas, including non-Hodgkin's lymphomas. Applicants further reiterate their arguments presented in Paper No. 8, pages 4-5. However, these arguments have been carefully considered but are not found persuasive for the reasons of record.

Claims 1,3, 5, 7 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,776,456 (Anderson *et al.* ) as evidenced by Murphy *et al.* (Clinical Oncology, 2<sup>nd</sup> edition, 1995, American Cancer Society, Inc., pages 392,408) and Kuppers *et al.* (Ann Oncol, 1998, Vol. 9 Suppl 5, abstract ) in further view of Yoneda *et al.* (US Patent No. 5,626,845, 1997). Applicants reiterate their arguments with regards to the above rejections. Thus, for the reasons of record and for the reasons set forth above, applicants' arguments are not found persuasive and the rejection is maintained.

Claims 1, 3-5, and 7 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a central nervous system (CNS) lymphoma in a mammal that has been diagnosed with said lymphoma, does not reasonably provide enablement for the claims as broadly drawn for the reasons of record. Applicants have argued that the amendment to the claims obviates this rejection. However, since the amendments were not entered, the rejection is maintained for the reasons of record.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
August 11, 2003

